

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MHAIRI PORTEOUS, Derivatively and on
behalf of BRAINSTORM CELL
THERAPEUTICS INC.,

Plaintiff,

v.

CHAIM LEBOVITS, STACY LINDBORG,
RALPH KERN, JACOB FRENKEL, IRIT
ARBEL, JUNE ALMENOFF, NIR NAOR,
ANTHONY POLVERINO, URI
YABLONKA, MENGHIS BAIRU,
MALCOLM TAUB, JEROLD CHUN,
STANLEY H. APPEL, and AMIT BAR-OR,

Defendants,

and

BRAINSTORM CELL THERAPEUTICS,
INC.,

Nominal Defendant.

Case No:

**VERIFIED SHAREHOLDER
DERIVATIVE ACTION**

JURY TRIAL DEMANDED

Plaintiff Mhairi Porteous (“Plaintiff”), by and through her counsel, derivatively on behalf of Nominal Defendant Brainstorm Cell Therapeutics, Inc. (“Brainstorm” or the “Company”), submits this Verified Shareholder Derivative Complaint against the Individual Defendants (as defined below) and allege the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, her counsels’ investigation, which included, *inter alia*, review and analysis of: (i) regulatory filings made by Brainstorm with the U.S. Securities and Exchange Commission (“SEC”); (ii) press releases issued and disseminated by Brainstorm; (iii)

the complaint and other pleadings filed in a consolidated class action lawsuit captioned *Sporn v. Brainstorm Cell Therapeutics, Inc., et al.*, Case No. 1:23-cv-09630 (the “Securities Class Action”), pending in this Court; and (iv) other publicly available information, including media and analyst reports, concerning Brainstorm. The Securities Class Action asserts claims against Brainstorm, and Individual Defendants Chaim Lebovits (“Lebovits”) and Stacy Lindborg (“Lindborg”), for violations of the anti-fraud provisions of the federal securities laws arising out of the alleged issuance of false and misleading statements of material fact and the alleged omission to state material facts necessary to make other statements made not misleading with respect to Brainstorm’s attempts to obtain U.S. Food and Drug Administration (“FDA”) approval in connection with NurOwn, between August 15, 2022 and September 27, 2023 (the “Relevant Period”).

NATURE OF THE ACTION AND OVERVIEW

1. This is a shareholder derivative action asserting claims for breach of fiduciary duty against certain current and former officers and members of the Company’s Board of Directors (the “Board”).

2. Brainstorm, a biotechnology company, engages in the development and commercialization of autologous cellular therapies for the treatment of neurodegenerative diseases. The Company, through its NurOwn proprietary cell therapy platform, leverages cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells to secrete high levels of neurotrophic factors, modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival, and enhance neurological function.

3. The Company is developing NurOwn, which has completed a Phase III clinical trial for the treatment of amyotrophic lateral sclerosis; Phase II clinical trial for the treatment of

progressive multiple sclerosis; and for the treatment of Alzheimer's disease, as well as for other neurodegenerative diseases.

4. On August 15, 2022, before market hours, the Company issued a press release announcing its submission of a Biologics License Application ("BLA") to the FDA for NurOwn for the treatment of amyotrophic lateral sclerosis ("ALS"). The press release touted the effectiveness of NurOwn. The Company subsequently filed a BLA for NurOwn on September 9, 2022.

5. On October 12, 2022, after market hours, the Company issued a press release announcing the presentation of new biomarker analyses from its NurOwn Phase 3 ALS study.

6. Brainstorm received a refusal to file letter from the FDA on November 8, 2022. However, Brainstorm submitted its application over the FDA's protest downplaying the seriousness of the FDA's refusal to file letter.

7. On March 27, 2023, before market hours, the Company issued a press release announcing the FDA Advisory Committee Meeting to review the Company's BLA of NurOwn. The press release continued to tout NurOwn's effectiveness.

8. On March 30, 2023, before market hours, the Company issued a press release reminding investors about the upcoming FDA Advisory Committee Meeting. The press release once again expressed NurOwn's purported effectiveness.

9. On June 6, 2023, before the market opened, the Company issued a press release announcing the FDA's plan to meet on September 27, 2023 to review the BLA for NurOwn. The press release continued to make positive statements about NurOwn.

10. On August 14, 2023, before the market opened, the Company issued a press release restating its preparations for its meeting with the FDA on September 27, 2023 to review the BLA for NurOwn. The press release repeated the positive statements about NurOwn.

11. These positive statements regarding NurOwn were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to the Individual Defendants or recklessly disregarded by them. Specifically, the Individual Defendants made false and/or misleading statements and/or failed to disclose that: (1) Brainstorm downplayed the severity of the FDA's refusal to file letter; (2) Brainstorm continued to conceal the risks associated with the submission of the BLA; and (3) as a result, the Individual Defendants' statements about Brainstorm's business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

12. The Individual Defendants breached their fiduciary duties of loyalty, good faith, due care, oversight, and candor by knowingly engaging in the deceptions alleged herein.

13. As a direct and proximate result of the Individual Defendants' breaches of fiduciary duties, Brainstorm has sustained damages as described below.

JURISDICTION AND VENUE

14. This Court has diversity jurisdiction conferred by 28 U.S.C. § 1332. Plaintiff and the Individual Defendants are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

15. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

16. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

17. The Court has personal jurisdiction over each of the Defendants because each Defendant is either a corporation incorporated in this District, or he or she is an individual who has minimum contacts with this District to justify the exercise of jurisdiction over them.

18. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

PARTIES

19. Plaintiff is a current shareholder of Brainstorm common stock and has continuously held Brainstorm common stock at all relevant times. Plaintiff is a citizen of the Country of the United Kingdom.

20. Defendant Brainstorm is a biotechnology company, which develops and commercializes autologous cellular therapies for the treatment of neurodegenerative diseases, including Amyotrophic Lateral Sclerosis, Progressive Multiple Sclerosis, Alzheimer's disease, and other neurodegenerative diseases. Its pipeline, NurOwn proprietary cell therapy platform, leverages cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells to secrete high levels of neurotrophic factors, modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival, and improve neurological function. Brainstorm is incorporated in Delaware and its principal office is located at 1325 Avenue of Americas, 28th Floor, New York, New York, 10019. Brainstorm securities trade on the Nasdaq Stock Market under the ticker symbol "BCLI."

21. Defendant Lebovits has served as the Company's President since July 2007 and Co-Chief Executive Officer ("CEO") since September 2015. His total annual compensation for the years 2021 and 2022, respectively, was \$1,128,349 and \$ 1,117,966. Upon information and belief, Defendant Lebovits is a citizen of the State of New York.

22. Defendant Lindborg has served as the Company's Co-CEO since June 2020. Defendant Lindborg's total annual compensation for the years 2021 and 2022, respectively, was

\$736,680 and \$851,543. Upon information and belief, Defendant Lindborg is a citizen of the Commonwealth of Massachusetts.

23. Defendant Dr. Ralph Kern (“Kern”) and the Company entered into an employment agreement on February 28, 2017, effective March 6, 2017, for Kern to be the Chief Medical Officer. Upon information and belief, Defendant Kern is a citizen of the State of New York. Defendant Kern’s total annual compensation for the years 2021 and 2022, respectively, was \$938,833 and \$812,559.

24. On January 3, 2023, the Company and Dr. Kern entered into a separation agreement (the “Kern Separation Agreement”). Effective as of January 3, 2023, the Kern Separation Agreement terminated the Kern Employment Agreement. The Kern Separation Agreement provides, among other things, that Kern shall be eligible to receive, in exchange for agreeing and complying with the terms of the Kern Separation Agreement, including the release it contains, (i) a payment of \$250,000, payable within 90 days of January 20, 2023 (the “Kern Separation Date”), (ii) a grant of 150,000 non-restricted shares of Common Stock, which shall be granted 90 days after the Kern Separation Date, and (iii) a payment of \$125,000 as prorated annual bonus compensation, payable within 30 days of the Kern Separation Date. In addition, all unvested equity and/or equity-based awards that would have vested during the six months following the Kern Separation Date shall vest immediately upon the Kern Separation Date and be treated as described in the preceding sentence.

25. Effective as of the Kern Separation Date, Kern became a member of the Company’s Scientific Advisory Board, which advises the management team on scientific matters such as research, clinical trials and drug development. In connection with Kern’s appointment to the Scientific Advisory Board, the Company and Kern entered into a consulting agreement (the “Kern

Consulting Agreement”), effective as of the Kern Separation Date. Pursuant to the Kern Consulting Agreement, Kern will provide scientific advisory board consulting services to the Company for \$450 per hour for up to ten hours each month, for an initial term of two years, unless earlier terminated in accordance with the terms of the Kern Consulting Agreement.

26. Defendant Dr. Irit Arbel (“Arbel”), one of the Company’s co-founders, joined the Company in May 2004 as a director and served as President of the Company for six months. Currently, Arbel is the Vice-Chairperson of the Board, a member of the Audit Committee, and the Chair of the Governance, Nominating and Compensation Committee. Upon information and belief, Defendant Arbel is a citizen of the Country of Israel.

27. Defendant Dr. Menghisteab Bairu (“Bairu”) joined the Company in October 2021 as a director. Upon information and belief, Defendant Bairu is a citizen of the State of California.

28. Defendant Dr. Jacob Frenkel (“Frenkel”) joined the Company in March 2020 as a director and Chairperson. Upon information and belief, Defendant Frenkel is a citizen of the State of New York.

29. Defendant Nir Naor (“Naor”) joined the Company in June 2023 as a director and is a member of the Governance, Nominating and Compensation Committee, and Chair of the Audit Committee. Upon information and belief, Defendant Naor is a citizen of the State of Georgia.

30. Defendant Dr. Anthony Polverino (“Polverino”) joined the Company on February 5, 2018 as a director. Defendant Polverino is a member of the Governance, Nominating and Compensation Committee. Upon information and belief, Defendant Polverino is a citizen of the State of Washington.

31. Defendant Uri Yablonka (“Yablonka”) joined the Company on June 6, 2014 as Chief Operating Officer and as a director. On March 6, 2017 he was appointed Executive Vice

President, Chief Business Officer and ceased to serve as the Company's Chief Operating Officer. Upon information and belief, Defendant Yablonka is a citizen of the State of New Jersey.

32. Defendant Dr. June S. Almenoff ("Almenoff") joined the Company on February 26, 2017 as a director. Defendant Almenoff is a member of the Audit Committee. Upon information and belief, Defendant Almenoff is a citizen of the State of North Carolina.

33. Defendant Malcolm Taub ("Taub") joined the Company in March 2009 as a director. Defendant Taub resigned from the Board on June 15, 2023. Prior to his resignation, Defendant Taub was Chairman of the Audit Committee. Upon information and belief, Defendant Taub is a citizen of the State of New York.

34. Defendant Jerold Chun, MD, PhD ("Chun") is a member of the Company's Scientific Advisory Board. The Scientific Advisory Board advises the management team on scientific matters such as research, clinical trials, and drug development. Upon information and belief, Defendant Chun is a citizen of the State of California.

35. Defendant Stanley H. Appel, MD ("Appel") is a member of the Company's Scientific Advisory Board. Upon information and belief, Defendant Appel is a citizen of the State of Texas.

36. Defendant Amit Bar-Or, MD ("Bar-Or") is a member of the Company's Scientific Advisory Board. Upon information and belief, Defendant Bar-Or is a citizen of the Country of Canada.

37. The defendants referenced above in ¶¶ 21-36 are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

38. By reason of their positions as officers and/or directors of the Company and because of their ability to control the business and corporate affairs of the Company, the Individual

Defendants owed the Company and its stockholders the fiduciary obligations of good faith, loyalty, and candor and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its stockholders so as to benefit all stockholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to the Company and its stockholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

39. The Individual Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

40. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Brainstorm were required to, among other things:

A. ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

B. conduct the affairs of the Company in a lawful, efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

C. properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about

the Company's financial results and prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

D. remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

E. ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state, and local laws, rules, and regulations.

41. Each Individual Defendant, as a director and/or officer, owed to the Company and its stockholders the fiduciary duties of loyalty, good faith and candor in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a conscious disregard for their duties to the Company and its stockholders that Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

42. As noted in the Company's latest Proxy Statement filed with the SEC on November 8, 2023 (the "2023 Proxy"):

Risk Management and Oversight Process

The Board takes an active role, as a whole and at the committee level, in overseeing management of our Company's risks. Generally, the entire Board, the Audit Committee and the GNC Committee are involved in overseeing risks associated

with the Company and monitor and assess those risks in reviews with management and with the Company's outside advisors and independent registered public accounting firm. The Audit Committee reviews regulatory risk, operational risk and enterprise risk, particularly as they relate to financial reporting, on a regular basis with management, the Company's independent registered public accounting firm and the Company's outside consultants and advisors. In its regular meetings, the Audit Committee discusses the scope and plan for the internal audit and includes management in its review of accounting and financial controls, assessment of business risks and legal and ethical compliance programs. The GNC Committee monitors the Company's governance and succession risk by review with management and outside advisors. The GNC Committee also monitors Chief Executive Officer succession and the Company's compensation policies and related risks by reviews with management. The GNC Committee periodically reviews our compensation programs for employees to assure that these programs do not create risks that are reasonably likely to have a material adverse effect on the company.

43. The 2023 Proxy also states the following:

The Audit Committee operates under a written charter which is available on our website at www.brainstorm-cell.com. The Audit Committee's responsibilities include, among other things:

- appointing, evaluating, retaining and, when necessary, terminating the engagement of the independent auditor;
- taking, or recommending that the Board take, appropriate action to oversee the independence of the independent auditor;
- setting the compensation of the independent auditor;
- preapproving all audit services to be provided to the Company, and all other services to be provided to the Company by the independent auditor;
- overseeing the work of the independent auditor;
- reviewing and discussing with the Company's management and independent auditor the Company's audited financial statements;
- recommending whether the Company's audited financial statements be included in our Annual Report on Form 10-K;
- preparing an annual report for inclusion where necessary in the proxy statement of the Company relating to its annual meeting;
- coordinating the Board's oversight of the Company's internal control over financial reporting, disclosure controls and procedures and code of conduct;

- reviewing all related party transactions, and approving all such transactions; and
- engaging and paying such independent legal, accounting and other advisors as it deems necessary or appropriate to carry out its responsibilities.

44. As noted above, the Company also maintains a Code of Conduct (the “Code”). The Code states in pertinent part:

Compliance with Laws, Rules and Regulations

The Company requires that all employees, officers and directors comply with all laws, rules and regulations applicable to the Company wherever it does business. You are expected to use good judgment and common sense in seeking to comply with all applicable laws, rules and regulations and to ask for advice when you are uncertain about them.

* * *

Honest and Ethical Conduct and Fair Dealing

Keeping the best interests of the Company in mind, employees, officers and directors should endeavor to deal honestly, ethically and fairly with the Company’s suppliers, customers, competitors and employees. Statements regarding the Company’s products and services must not be untrue, misleading, deceptive or fraudulent. You must not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other unfair-dealing practice.

* * *

Accuracy of Books and Records and Public Reports

Employees, officers and directors must honestly and accurately report all business transactions. You are responsible for the accuracy of your records and reports. Accurate information is essential to the Company’s ability to meet legal and regulatory obligations.

All Company books, records and accounts shall be maintained in accordance with all applicable regulations and standards and accurately reflect the true nature of the transactions they record. The financial statements of the Company shall conform to generally accepted accounting principles and the Company’s accounting policies. No undisclosed or unrecorded account or fund shall be established for any purpose. No false or misleading entries shall be made in the Company’s books or records for any reason, and no disbursement of corporate funds or other corporate

property shall be made without adequate supporting documentation (other than de minimis amounts).

It is the policy of the Company to provide full, fair, accurate, timely and understandable disclosure in reports and documents filed with, or submitted to, the Securities and Exchange Commission and in other public communications.

SUBSTANTIVE ALLEGATIONS

COMPANY BACKGROUND

45. Brainstorm, a biotechnology company, engages in the development and commercialization of autologous cellular therapies for the treatment of neurodegenerative diseases. The Company, through its NurOwn proprietary cell therapy platform, leverages cell culture methods to induce autologous bone marrow-derived mesenchymal stem cells to secrete high levels of neurotrophic factors, modulate neuroinflammatory and neurodegenerative disease processes, promote neuronal survival, and enhance neurological function.

46. The Company is developing NurOwn, which has completed a Phase III clinical trial for the treatment of amyotrophic lateral sclerosis; Phase II clinical trial for the treatment of progressive multiple sclerosis; and for the treatment of Alzheimer's disease, as well as for other neurodegenerative diseases.

47. The Company was formerly known as Golden Hand Resources Inc. and changed its name to Brainstorm Cell Therapeutics Inc. in November 2004. Brainstorm Cell Therapeutics Inc. was incorporated in 2000 and is headquartered in New York, New York.

THE INDIVIDUAL DEFENDANTS MATERIALLY FALSE AND MISLEADING STATEMENTS

48. On August 15, 2022, before market hours, the Company issued a press release announcing its submission of a BLA to the FDA for NurOwn for the treatment of ALS. The press release touted the effectiveness of NurOwn, by stating the following, in relevant part:

BrainStorm announces decision to submit a BLA to the FDA for NurOwn® for the treatment of ALS

“Brainstorm Cell Therapeutics is at a pivotal moment as a company as we finalize the regulatory filing for NurOwn® in the treatment of ALS. *The continued analysis and the feedback received from the many scientific presentations of NurOwn’s® Phase 3 data have uncovered key insights that furthered our understanding of the product mechanism of action and therapeutic potential and strengthened the conclusions of NurOwn’s® efficacy,*” said Chaim Lebovits, Chief Executive Officer. *“After carefully considering these learnings, the totality of the evidence from NurOwn’s® clinical studies, and the feedback received from key opinion leaders and the broader ALS community, we will submit a Biologics License Application to the FDA.* We are deeply grateful to the ALS clinical experts, members of the ALS community and faithful investors for their contribution to the development of NurOwn® and what it may mean to those living with ALS. Their contributions and commitment made our current progress possible and continue to inspire us as we prepare for the considerable work ahead. We intend to provide additional updates upon learning whether the FDA files our BLA submission.”

New clinical analyses strengthen the conclusions from NurOwn’s® Phase 3 clinical trial

A correction was made to the *Muscle and Nerve* publication from December 2021 describing the results of NurOwn’s® Phase 3 clinical trial in ALS following new clinical analyses which strengthen the Company’s original conclusions from the trial. The correction results in a statistically significant treatment difference ($p=0.050$) of more than 2 points for an important secondary endpoint, average change from baseline in ALSFRS-R, in the pre-specified efficacy subgroup of participants with a baseline score of at least 35. Analyses reported in the original publication utilized an efficacy model that unintentionally deviated from the trial’s pre-specified statistical analysis plan by erroneously incorporating interaction terms between the subgroup and treatment. The newly published results, which includes supporting information to the publication, employ the efficacy model as pre-specified in the trial’s statistical analysis plan, correcting the analyses. The correction also relates to the other subgroup analyses published for this endpoint, demonstrating that all subgroups with ALSFRS-R baseline scores of at least 26 to 35 showed a statistically significant benefit following treatment with NurOwn® ($p \leq 0.050$) on this secondary endpoint.

(Emphasis added).

49. On October 12, 2022, after market hours, the Company issued a press release announcing the presentation of new biomarker analyses from its NurOwn Phase 3 ALS study. The press released continued to tout the effectiveness of NurOwn, stating the following, in relevant part:

“The new biomarker analyses presented today provide further evidence of NurOwn’s multifaceted mechanism of action and show consistent patterns in study participants regardless of the level of disease progression at baseline,” said Dr. Stacy Lindborg, Chief Development Officer at Brainstorm. “This compelling finding confirms the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints in our phase 3 trial and may further validate the results of subgroup analyses on clinical endpoints in our Phase 3 study which minimize the ALSFRS-R floor. When the subgroup of participants above 26 are analyzed, 2 points of function are preserved on average across 28 weeks in participants treated with NurOwn compared to placebo ($p < .05$). Moreover, statistical modeling identified biomarkers that have the potential to predict clinical response to NurOwn observed in the trial, with markers of neuroinflammation, neurodegeneration, and neuroprotection selected in the final model. ***Novel therapies that simultaneously target multiple pathways may offer great potential in the treatment of ALS and highlights the advantages that may come with NurOwn’s ability to simultaneously modulate multiple biological pathways.***

* * *

Biomarker Data

- An analysis was performed to evaluate the effects of NurOwn and placebo on cerebrospinal fluid (CSF) biomarkers across pathways important to ALS of neuroinflammation, neurodegeneration and neuroprotection. Additional goals were to understand the role that baseline ALSFRS-R values plays on biomarker trajectories and to understand the predictive power of biomarkers on clinical outcomes.
- As observed in earlier trials, NurOwn was shown to decrease biomarkers associated with neuroinflammation and neurodegeneration, and increase neuroprotective biomarkers over 20 weeks, demonstrating its multifaceted mechanism of action.
- ***New analyses looked at the trajectory of biomarkers for the subgroups of participants with baseline ALSFRS-R scores >25 and ≤ 25 , those most likely to be impacted by the floor effect of the scale. Decreases in neuroinflammatory and neurodegenerative markers and increases in neuroprotective markers in NurOwn treated participants compared to placebo were observed in both subgroups. These results indicate that NurOwn had similar biological effects on ALS participants regardless of the level of disease progression at baseline.***
- Further statistical modeling pre-specified prior to unblinding of the data identified three biomarkers that were predictive of clinical outcomes: baseline LAP, baseline neurofilament light (NfL) and mean change in

Galectin-1. These biomarkers relate to neuroinflammatory, neurodegenerative, and neuroprotective pathways, respectively.

- ***Chaim Lebovits, Chief Executive Officer of Brainstorm commented, “We are grateful to ALS ONE for the opportunity to present these important new data on NurOwn. The biomarker data and statistical analyses further our understanding of NurOwn’s mechanism of action and therapeutic potential.”***

(Emphasis added).

50. On November 10, 2022 the Company issued a press release entitled “BrainStorm Cell Therapeutics Receives Refusal to File Letter from FDA for its New Biologics License Application for NurOwn for the treatment of ALS.” The press release stated the following, in relevant part:

“While we are disappointed that the FDA has not accepted our BLA for NurOwn in ALS, we remain committed to NurOwn’s advancement as a treatment for this devastating disease. The company intends to request a Type A meeting and looks forward to continued discussions with the FDA,” said Chaim Lebovits, Chief Executive Officer of BrainStorm. “We continue to believe that NurOwn’s Phase 3 trial represents a significant contribution to ALS therapy and will continue to work tirelessly to address the needs of people living with ALS by advancing science and partnering with researchers around the world.”

The three, co-principal investigators of the NurOwn Phase 3 study were Dr. Robert Brown, Director of the Program in Neurotherapeutics at the University of Massachusetts Medical School, Dr. Merit Cudkowicz, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital and Dr. Tony Windebank, Professor of Neurology and Judith and James Pape Adams Foundation Professor of Neuroscience at Mayo Clinic.

Drs. Brown, Cudkowicz and Windebank jointly stated, ***“While the pre-specified primary outcome measure was not met, there were participants with beneficial clinical effects and overall changes in relevant biomarkers of drug effect. Understanding whether there are people with ALS who might respond better to NurOwn is important given the unmet therapeutic need.*** As the three co-PIs of the Phase 3 study of NurOwn, we support continued discussions with the FDA on the best path forward.”

BrainStorm completed a Phase 3 trial in 200 participants with ALS (Cudkowicz et al., 2022 Muscle and Nerve). In the attempt to examine a real-world

population, the study enrolled people with more advanced disease than other late-stage ALS trials. In fact, more than a third of these participants with advanced disease entered the trial with the one or more dimensions of physical function (e.g., dressing/hygiene, cutting food, walking) starting at the lowest possible score of 0 on the ALSFRS-R; thereby preventing the measurement of further deterioration. A pre-specified subgroup of participants, with baseline ALSFRS-R³⁵, which controls for this “scale effect” showed a trend to a meaningful increase in the clinical response with NurOwn compared to placebo. The secondary endpoint, average ALSFRS-R change from baseline to 28 weeks in this subgroup, was statistically significant ($p=0.050$, Muscle and Nerve Supplemental File and Muscle and Nerve Erratum). In addition, post-hoc sensitivity analyses were presented last week (21st Annual NEALS Meeting 2022) which also showed a statistical trend towards a clinically meaningful treatment effect with NurOwn across subgroups, and one that is consistent with the pre-specified subgroup of participants with less advanced ALS at baseline. ***Finally, biomarker data in all trial participants also showed consistent patterns of NurOwn reducing markers of inflammation and neurodegeneration, and increasing neuroprotective and anti-inflammatory markers relative to placebo, further supporting the notion that trial participants taking NurOwn are indeed experiencing a positive biological effect (ALS ONE Research Symposia 2022).***

(Emphasis added).

51. This announcement shocked the market. Brainstorm’s share price fell \$1.22 per share, or 42.21%, to close at \$1.67 per share on November 10, 2023.

52. On November 14, 2022, before market hours, the Company issued a press release on a Form 8-K filed with the SEC announcing its request for a Type A meeting with the FDA to “facilitate NurOwn’s advancement following receipt of a refusal to file letter regarding the Company’s new [BLA].” The press release downplayed the refusal to file letter, continuously touting NurOwn’s effectiveness. The press release stated the following, in relevant part:

“Our commitment to ALS patients and our belief in NurOwn’s potential to address their unmet medical needs remains unchanged, despite our receipt of a refusal to file letter regarding our new Biologics License Application,” said Chaim Lebovits, Chief Executive Officer of Brainstorm. “Our next step is to request a Type A meeting with the FDA, which will help us explore the best path forward to accomplish our goal of providing ALS patients with broad access to NurOwn. We believe that an important part of the regulatory process will be an FDA Advisory Committee meeting to discuss NurOwn, as this will allow a fair hearing in an open and transparent setting. We are grateful for the support we

are receiving and look forward to providing more information on our Earnings Call around the FDA feedback we have received, and our next steps.”

Third Quarter 2022 and Recent Highlights

- Additional analyses from NurOwn’s Phase 3 ALS trial that account for measurement limitations in the lower part of the Revised ALS Functional Rating Scale (ALSFRS-R) were presented at the 21st Annual NEALS Meeting. *These analyses add to the robust body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS, as two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo.*
- Biomarker analyses from NurOwn’s Phase 3 ALS trial presented at the 5th Annual ALS ONE Research Symposium confirmed the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints. *The new biomarker data presented indicate that NurOwn had similar biological effects on Phase 3 trial participants regardless of the level of disease progression at baseline, providing further evidence confirming NurOwn’s multifaceted mechanism of action. Furthermore, biomarkers spanning the 3 key pathways of neurodegeneration, neuroinflammation and neuroprotection were identified by a pre-specified model linking the changes in biomarkers in participants treated with NurOwn to the clinical outcomes observed in the trial.* The presentation was delivered by Dr. Stacy Lindborg, Executive Vice President and Chief Development Officer at Brainstorm.
- Full results from a single-arm, Phase 2 trial of NurOwn were published in the peer-reviewed Multiple Sclerosis Journal. The results demonstrate NurOwn’s safety and provide preliminary evidence of efficacy in patients with progressive multiple sclerosis (MS). Treatment with NurOwn resulted in large, clinically meaningful improvements in some progressive MS patients, as defined by response criteria, across all endpoints measured. These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. In addition, biomarker analyses confirmed NurOwn’s proposed mechanism of action in progressive MS by showing consistent treatment effects in neuroinflammation and neuroprotection pathways.
- Biomarker data from the Phase 2 trial of NurOwn in progressive MS was presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental

Therapeutics, Mellen Center for MS Treatment and Research. The presented data provide important biological context for the trial's observed clinical outcomes, as they showed NurOwn treatment resulting in robust increases in neuroprotective biomarkers in cerebrospinal fluid.

(Emphasis added).

53. On March 27, 2023, before market hours, the Company issued a press release announcing the FDA Advisory Committee Meeting to review the Company's BLA of NurOwn. The press release continued to express NurOwn's effectiveness, stating the following, in relevant part:

Given the goal to proceed to an ADCOM as expeditiously as possible, BrainStorm requested that the Center for Biologics Evaluation and Research (CBER) utilize the FDA's File Over Protest procedure and has filed an amendment to the BLA which responds to most of the outstanding questions the FDA has posed.

"The FDA provided us with more than one path to an ADCOM for NurOwn. Our goal has always been to make NurOwn available to people living with ALS as quickly as possible, therefore we chose the File Over Protest pathway since this offered the fastest path to an ADCOM and regulatory decision relative to other pathways provided by the FDA," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. ***"The ALS community needs additional treatment options now, and we firmly believe our data support regulatory approval of NurOwn. We are grateful to the FDA for the opportunity to have the clinical evidence supporting NurOwn reviewed."***

Stacy Lindborg, Ph.D., BrainStorm's Co-Chief Executive Officer commented, "ALS is a horrific, neurodegenerative disease that moves at a terrifying speed, robbing people of their ability to move, speak, eat, and breathe. Securing an ADCOM represents an important step towards our goal of making NurOwn broadly available to individuals living with ALS who are in urgent need of new, effective therapies. The meeting will provide an open forum for BrainStorm and the FDA, together with medical experts, statisticians, and the ALS community, to thoughtfully review all available evidence supporting NurOwn. We remain confident in NurOwn and we are committed to doing everything in our power to make the product available quickly to people living with ALS. We look forward to a robust scientific discussion."

(Emphasis added.)

54. On March 30, 2023, before market hours, the Company issued a press release reminding investors about the upcoming FDA Advisory Committee Meeting. The press release continued to express NurOwn's effectiveness, stating the following, in relevant part:

"Our priority in 2023 is to advance NurOwn® through the regulatory process as expeditiously as possible, including making preparations for our upcoming Advisory Committee Meeting," said BrainStorm's President and Chief Executive Officer (CEO) Chaim Lebovits and Co-CEO Dr. Stacy Lindborg in a joint statement. ***"The ADCOM will provide an invaluable opportunity for an open and thoughtful discussion among BrainStorm, regulators, ALS experts, and other key stakeholders on both the urgent need for new ALS therapies and the robust and intricate dataset that we believe supports NurOwn's approval. As we move towards this important event, our clinical trial results and experienced team give us confidence in our ability to secure a successful outcome and execute on our mission of improving the lives of individuals with ALS."***

Fourth Quarter 2022 and Recent Highlights

U.S. Food and Drug Administration (FDA) notified BrainStorm in a written communication that the Agency will hold an Advisory Committee Meeting (ADCOM) to review the company's Biologics License Application (BLA) for NurOwn for the treatment of amyotrophic lateral sclerosis (ALS).

- To meet its goal of proceeding to an ADCOM as expeditiously as possible, BrainStorm utilized the FDA's File Over protest procedure to return the BLA to active review and filed an amendment which responds to most of the outstanding questions previously posed by the FDA. The Agency notified Brainstorm that it will set a date for the ADCOM as well as a Prescription Drug User Fee Act (PDUFA) target action date in due course.
- A presentation at the 2023 MDA Clinical and Scientific Conference delivered by Dr. Lindborg featured post hoc sensitivity analyses from NurOwn's Phase 3 ALS trial. The presentation showed that a floor effect was observed in the PRO-ACT database, and a pattern of a plateau in ALSFRS-R total score was accompanied by scale items of 0 suggesting measurement challenges in those with advanced ALS due to the floor effect of the ALSFRS-R in the NurOwn phase 3 trial and historical studies which are included in the PRO-ACT database. ***Analyses conducted in participants not impacted by the floor effect at baseline of the NurOwn phase 3 trial revealed statistically significant, clinically meaningful effects with NurOwn on the primary and key secondary endpoints.***
- Additional analyses from the Phase 3 trial of NurOwn in ALS were featured in a presentation at the 21st Annual NEALS Meeting. ***These***

analyses further strengthened the body of evidence supporting a clinically meaningful treatment effect with NurOwn in ALS. Two complementary post-hoc sensitivity analysis methods showed that, after controlling for the impact of the ALSFRS-R floor effect, participants treated with NurOwn had a higher rate of clinical response and less function lost across 28 weeks compared to placebo. The presentation was co-delivered by Dr. Lindborg and Merit Cudkiewicz, MD, MSC, Chief of Neurology at Massachusetts General Hospital, Julieanne Dorn Professor of Neurology at Harvard Medical School, and Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital.

- Biomarker data from the Phase 3 trial of NurOwn in ALS were featured in a presentation delivered by Dr. Lindborg at the 5th Annual ALS ONE Research Symposium. The data showed NurOwn modulated pathways related to neurodegeneration, neuroinflammation, and neuroprotection, with changes that were consistent regardless of a participant's level of disease progression at baseline. These data provide further evidence of NurOwn's multifaceted mechanism of action and of the importance of accounting for ALSFRS-R floor effects when evaluating clinical endpoints.
- Findings from the Phase 3 trial of NurOwn in ALS, including biomarker data and analyses accounting for the ALSFRS-R floor effect, were presented at the 13th Annual California ALS Research Summit by Dr. Lindborg. *The presentation demonstrated that NurOwn had significantly better outcomes in analyses controlling for the floor effect. Outcomes that aligned with historical data and power calculations of the trial.*
- Biomarker data from the Phase 2 trial of NurOwn in progressive multiple sclerosis were presented at the 38th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). *The data showed robust increases in levels of neuroprotective biomarkers in cerebrospinal fluid with NurOwn treatment, thereby providing important biological context for clinical outcome data showing large, clinically meaningful improvements in some trial participants, as defined by response criteria, across all endpoints measured.* These observed improvements diverged from what was seen in matched patients with progressive MS from the Comprehensive Longitudinal Investigation of Multiple Sclerosis (CLIMB) registry. The presentation was delivered by Jeffrey Cohen, MD, Hazel Prior Hostetler Endowed Chair and Professor of Neurology, Cleveland Clinic Lerner College of Medicine, Director, Experimental Therapeutics, Mellen Center for MS Treatment and Research.

(Emphasis added).

55. On June 6, 2023, before the market opened, the Company issued a press release announcing the FDA's plan to meet on September 27, 2023 to review the BLA for NurOwn. The press release continued to make positive statements about NurOwn, stating the following, in relevant part:

"We are encouraged by the regulatory flexibility that the FDA has shown over the last year in ALS broadly, and with respect to NurOwn in particular, and believe an Advisory Committee meeting is good for patients," said Chaim Lebovits, BrainStorm President & CEO. "We are of course deeply committed to the scientific and regulatory process, which includes continuing research to confirm the results of the NurOwn clinical program and are working with ALS experts in designing a rigorous clinical study to answer important questions about this therapy and inform further research on ALS."

Stacy Lindborg, Ph.D., BrainStorm co-CEO, commented: "***We welcome the opportunity to present our data at the forthcoming ADCOM. We remain confident in NurOwn and believe our data support regulatory approval.*** As is the case with most ALS research, our clinical program generated complex results, which deserve a thoughtful and holistic review by scientists, ALS experts, FDA reviewers, advocates, and patients. We believe this approach honors the needs of those living with ALS and offers the greatest promise for BrainStorm to fulfill our commitment to the ALS community."

(Emphasis added).

56. On August 14, 2023, before the market opened, the Company issued a press release restating its preparations for its meeting with the FDA on September 27, 2023 to review the BLA for NurOwn. The press release continued to make positive statements about NurOwn, stating the following, in relevant part:

BrainStorm's immediate priorities are to prepare for the upcoming ADCOM meeting to review the BLA for NurOwn®, scheduled for September 27, and complete preparations for commercial launch. The Company's senior team is working with expert consultants to ensure it will deliver a compelling presentation to the ADCOM and is prepared to address the questions that the FDA and members of the committee might raise.

"We appreciate the FDA's guidance and input throughout the review process, which will be instrumental in making a policy decision that meets the needs of those living with ALS," said Chaim Lebovits, President and Chief Executive Officer of BrainStorm. "In parallel with the regulatory work, we are preparing

the company for success, with the goal of making NurOwn available to patients, if approved in December.”

Dr. Stacy Lindborg, Co-Chief Executive Officer of BrainStorm commented, “We look forward to discussing NurOwn’s full dataset at the forthcoming ADCOM meeting. Our clinical program has generated complex results, and the ADCOM meeting will provide us with the opportunity for a thoughtful discussion with scientists, ALS experts, FDA reviewers, advocates, and patients. ***We have full confidence in the data we have compiled, and believe that a comprehensive analysis of our results strongly supports NurOwn’s clinically meaningful effectiveness. In addition, we continue to share our data with the ALS community at scientific meetings and recently delivered an important presentation at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. The data from this new analysis showed that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including neurofilament light (NfL). Reductions in plasma NfL are believed to be a predictor of clinical benefit in ALS.***”

Second Quarter 2023 and Recent Highlights

Clinical and regulatory

- The U.S. Food and Drug Administration (FDA) notified BrainStorm that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee to review the BLA for NurOwn® has been scheduled for September 27, 2023. In addition, BrainStorm’s BLA for NurOwn has been assigned a PDUFA action date targeted to occur by December 8, 2023.
- In July 2023, new biomarker data from the Phase 3 trial of NurOwn were presented at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. ***These data show that treatment with NurOwn significantly elevated markers of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, including NfL over time compared to placebo in all trial participants. It is believed that reductions in plasma NfL are reasonably likely to predict clinical benefit in ALS.***

(Emphasis added).

57. The statements contained in ¶¶ 52-58 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company’s business, operations, and prospects, which were known to the Individual Defendants

or recklessly disregarded by them. Specifically, the Individual Defendants made false and/or misleading statements and/or failed to disclose that: (1) Brainstorm downplayed the severity of the FDA's refusal to file letter; (2) Brainstorm continued to conceal the risks associated with the submission of the BLA; and (3) as a result, the Individual Defendants' statements about Brainstorm's business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH BEGINS TO EMERGE

58. On September 27, 2023, the Company announced in a press release the results of the FDA's review of its BLA. Members of the Cellular, Tissue, and Gene Therapies Advisory Committee voted 17 to 1 that there was not substantial evidence to show NurOwn's effectiveness. The press release stated the following, in relevant part:

Today the Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for treatment of mild to moderate ALS.

“The Committee's vote was a sad outcome for the ALS community, who have too few options to help manage this merciless and deadly disease,” said Stacy Lindborg, PhD, co-CEO of BrainStorm. “We firmly believe that the totality of data presented for NurOwn today provide a compelling case for approval, with clinical evidence in those with less advanced disease supported by strong and consistent biomarker data that are predictive of clinical response. We truly did our best to make the NurOwn data clear to the FDA Advisory Committee. Unfortunately, had more time and opportunity been allowed, many remaining questions posed by Advisory Committee members could have been sufficiently addressed.”

59. The FDA briefing document revealed Brainstorm severely downplayed the risks associated with NurOwn, stating the following, in relevant part:

On initial receipt of the BLA, FDA determined that the submission was ***scientifically incomplete to demonstrate substantial evidence of effectiveness, and that the manufacturing information was grossly deficient to ensure adequate product quality***. Examples of critical information not provided in the BLA submission include missing or inadequate control of materials, validation of methods missing or incomplete, lack of data demonstrating manufacturing consistency, control strategy for prefilled syringe not provided, inadequate

manufacturing and testing facility information, and facilities not ready for inspection.

FDA therefore refused to file the submission and detailed these deficiencies in a Refuse to File (RTF) letter to the Applicant. The Applicant elected to request that the BLA to be filed over protest, and subsequently provided further retrospective analyses and biomarker results.

* * *

(2) Survival in the Phase 3 study was worse at study completion for subjects who received MSC-NTF. A total of 13 deaths occurred during the post-treatment follow up (28 weeks \pm 5 days) with 10 deaths (10/95) in the MSC-NTF group and 3 deaths (3/94) in the placebo group. The Kaplan-Meier (KM) estimate of survival at Week 28 (\pm 5 days) was 88.3% (95% CI: 79.3, 93.6) for the MSC-NTF group and 94.4% (95% CI: 81.2, 98.4) for the placebo group, with a nominal pvalue of 0.04 from unadjusted log rank test.

This outcome suggests the lack of efficacy of MSC-NTF on survival of patients with ALS.

(3) The Applicant performed three different retrospective analyses on an unblinded, post-hoc subgroup from the Phase 3 study, excluding in each certain subjects based on the assertion of a “floor effect” in the ALSFRS-R, according to different criteria. A floor effect refers to insensitivity of an outcome measure to differences at the lower end of an assessment scale. In this case, the Applicant claims that a floor effect results in plateauing of ALSFRS-R total scores over time, during which further deterioration of function cannot be measured. However, no floor effect was demonstrated in the analyses. In addition, floor effect would not be expected in the assessment of survival or biomarkers. ***Of note, when assessed by change in ALSFRS-R total score from baseline to Week 28, the MSCNTF subjects ostensibly affected by a “floor effect” in fact experienced a numerically larger decline in function over time than did the corresponding placebo subjects. This result indicates continued deterioration of function and suggests lack of treatment benefit for MSC-NTF subjects.***

(4) In the Phase 3 study, the Applicant collected cerebrospinal fluid (CSF) samples at baseline, Weeks 2, 4, 8, 12, 16, and 20 post-Treatment 1, and examined levels of multiple biomarkers. The Applicant then conducted numerous exploratory analyses, including multiple post hoc analyses, to evaluate the relationships between the selected biomarkers and clinical efficacy outcomes, to support the claim of effectiveness. ***Of note, there was a large amount of missing data for all biomarkers at Week 20 (~50%), the last time point for biomarker sample collection and the focused time point for biomarker analyses.***

* * *

The Applicant submitted the BLA on September 9, 2022. FDA conducted a filing review and determined that a substantive review could not be performed, because ***the BLA submission was scientifically incomplete and grossly deficient. Critical clinical and manufacturing deficiencies were identified. For clinical, the***

completed randomized, placebo-controlled clinical studies failed to show efficacy in their prospectively specified efficacy endpoints to demonstrate required substantial evidence of effectiveness. For manufacturing, the required Chemistry, Manufacturing, and Controls information covering several critical categories was not included in the application, and the level of information included was insufficient to perform a full assessment of product quality. Consequently, FDA issued a refuse-to-file letter to the Applicant on November 8, 2022.

* * *

FDA has concerns about the consistency of the manufacturing process and potential sources of product variability. It is important for licensure the Applicant demonstrate the manufacturing process is under a state of control. Chemistry, Manufacturing, and Control regulations are intended to assure that all subjects receive a quality product lot, including for safety and potency. Data supporting a product can come from in-process and final product properties, and from clinical data of safety and efficacy. ***However, for this BLA clinical data supporting safety for all patients is unclear, and efficacy has not been demonstrated.***

* * *

In addition to concerns about the adequacy of the existing manufacturing control strategy, there are concerns about manufacturing changes – either those that occurred during clinical development under IND, or for the proposed commercial product.

* * *

The primary efficacy endpoint and all key secondary endpoints failed to demonstrate efficacy of MSC-NTF compared to placebo (see Appendix III).

From the statistical perspective, when the primary efficacy endpoint in a clinical study fails to show statistical significance, the secondary efficacy endpoints cannot be tested with Type I error control.

In accordance with the Agency's discussions with the Applicant (Face-to-Face Meeting, November 18, 2019), however, FDA reviewed all primary and key secondary endpoint results. The Agency did so for several reasons: (1) although at that meeting the Applicant expressed openness to changing the primary efficacy endpoint from a slope-based analysis, FDA recommended against doing so, in order to avoid compromising the integrity of the Phase 3 study, which the Applicant had already initiated; (2) data for the outcome measures recommended by the Agency, such as CAFS or survival, were collected by the Applicant as secondary efficacy endpoints; and (3) FDA's willingness to exercise regulatory flexibility and desire to better inform subjects and stakeholders.

Primary Efficacy Endpoint

For the Applicant's primary efficacy endpoint, the percent of responders in the MSC-NTF group versus the placebo group did not show a statistically significant difference: the MSC-NTF group had 32.6% (31/95) responders and

the placebo group had 27.7% (26/94). The odds ratio after adjusting for the predefined covariates was 1.33 (95% CI: 0.63, 2.80) with a p-value of 0.45.

Key Secondary Efficacy Endpoints

All key secondary efficacy endpoints failed to show efficacy of MSC-NTF. For example, the least squares (LS) mean CAFS scores at Week 28 did not differ significantly between subjects in the MSC-NTF group and those in the placebo group (3.0: 96.5 versus 93.5; 95% CI: -11.4, 17.4; nominal p-value: 0.68). Similarly, there was minimal difference in LS mean change from baseline to Week 28 in ALSFRS-R total score (0.4: -5.5 versus -5.9; 95% CI: -1.47, 2.20; nominal p-value: 0.69).

* * *

In addition to this analysis, at the Type A meeting with the FDA after refusal to file of the BLA, the Applicant presented a third post-hoc floor effect analysis in which the no floor effect subgroup was defined as ALSFRS-R Item Level had no value 0 at baseline (Definition 3).

We will refer to these subgroups identified by the Applicant collectively as “no floor effect subgroup” and their respective complement “floor effect subgroup.” In the “no floor effect subgroup” identified by different definitions, some of the clinical endpoints showed “statistical significance” per the Applicant (Appendix IV); ***however, FDA believes these findings from the exploratory subgroup analysis can only be used for hypothesis generation, not as evidence of effectiveness to support approval, for the following reasons:***

(1) Post-hoc subgroup analyses in general have high risk of finding false positive results due to lack of control for multiple hypothesis testing and potential confounding due to imbalance in the measured/unmeasured baseline prognostic factors brought about by breaking the randomization. ***What is particularly concerning in this case is that there is no solid definition for the “no floor effect subgroup” (i.e., subgroup of trial subjects not impacted by floor effect).*** The “no floor effect subgroup” can potentially be defined in many ways, as illustrated by the three distinct subgroups identified by the Applicant, with various sample sizes (145, 159, and 106 subjects respectively). As one could define “no floor effect subgroup” in many ways, some of the “no floor effect subgroup” (like the three selected by the Applicant) may happen to show “positive” findings (i.e., findings that seem to suggest clinical efficacy) among many other subgroups that may show “negative” findings (i.e., findings that seem to suggest harm). These findings could be due to random chance, given the potentially large number of subgroups the Applicant could examine. ***Therefore, these findings need to be confirmed by additional adequate and well-controlled clinical study(ies) to establish their validity; these findings cannot be used as evidence of effectiveness to meet the statutory standard for this BLA.***

(2) ***MSC-NTF appeared to have a detrimental effect in the floor effect subgroups (Appendix IV).*** For example, the placebo group had a better CAFS ranking than the MSC-NTF group with a nominal p-value of 0.026 in the floor

effect subgroup defined by ALSFRS-R Total Score baseline ≤ 25 (Definition 1). The floor effect subgroups defined by the other two methods had the same issue. This is not surprising; given that the overall treatment effect was close to zero, when one subgroup happens to show a strong positive treatment effect, the complementary subgroup is highly likely to have a strong negative effect. The “negative” findings in the floor effect subgroup thus may well be false “negative,” in the same way that the “positive” findings in the no floor effect subgroup may well be false positives.

(3) FDA did not observe a “floor effect” in the floor effect subgroup defined by any of the three definitions identified by the Applicant. If there were a “floor effect” in the Applicant-identified floor effect subgroup, the ALSFRS-R total score post baseline would have been bounded by a “floor,” which would have prevented the score from much further decline. This is in direct contrast with the fact that the MSC-NTF “floor effect subgroup” had a drastically steeper decline in ALSFRS-R total score from baseline compared with the no floor effect subgroup or the placebo floor effect subgroup. At the same time, the magnitude of change between the placebo floor effect subgroup and the placebo no floor effect subgroup were comparable, which further puts into question the validity of the “floor effect” (Figure 12 [using Definition 1] and Figure 14 [using Definition 3]). In addition, the MSC-NTF floor effect subgroup showed substantially worse CAFS ranking than the no floor effect subgroups while the two placebo subgroups were comparable Figure 13. In conclusion, the lack of efficacy of MSC-NTF over placebo cannot be explained by a floor effect.

* * *

The Applicant conducted exploratory subgroup analysis of “rapid progressors” versus “slow progressors.” The Applicant defined “rapid progressors” as subjects with ≥ 2 points decline from screening to baseline (~ 3 months) in the ALSFRS-R total score; correspondingly, “slow progressors” were defined as subjects with < 2 points decline from screening to baseline in ALSFRS-R total score. As FDA stated in the November 18, 2019, Type C Meeting Summary:

“We interpret your Phase 2 data as evidence that your product is not effective in the treatment of ALS. Your proposal that your Phase 2 data suggest benefit for the ‘rapid progressors’ is most likely overinterpretation of your subgroup analyses. In subgroup analyses, the results for the ‘slow progressors’ could be interpreted to suggest that your product is harmful to some patients with ALS. However, such subgroup results, for both the ‘rapid progressors’ and the ‘slow progressors’, are most likely spurious and misleading, as is often the case for such subgroup analyses. We note that it is not clear why a product that you propose to have neuroprotective and immunomodulatory effects would be beneficial for some patients with ALS and harmful to other patients with ALS. Due to their inconsistency (i.e., opposite effects in ‘rapid progressors’ versus ‘slow progressors’), and the unclear biological plausibility for such inconsistency, your subgroup results do not support that your product has any meaningful activity in the treatment of ALS” [].

Despite FDA’s consistent concern about the definition of “rapid progressors,” and the exploratory nature of the subgroup findings, the Applicant decided to enroll only “rapid progressors” in the Phase 3 study. For that study, the Applicant modified the definition of a “rapid progressor” to be subjects who experienced at least a 1.0-point decline in ALSFRS-R per month, on average, during the 3-month pretreatment period.

* * *

In Study BCT-002-US, the biomarker analyses were limited by the large amount of missing data. Biomarker data were only collected up to Week 20, but the efficacy data were collected up to Week 28. At Week 20, the key biomarkers that the Applicant identified, NfL, galectin-1, MCP-1, VEGF-A, and LAP, had up to approximately 50% missing data. In general, this degree of missing data compromises the validity of the analyses and could lead to over-estimation of the correlations between the biomarkers and efficacy endpoints. This missing data problem was further exacerbated when those post-hoc subgroup analyses were conducted based on different “floor effect” hypothesis.

Although the Applicant added the biomarker addendum to the statistical analysis plan before the data were unblinded, numerous biomarker analyses were proposed without multiplicity adjustment or formal hypothesis testing. The results from those biomarker analyses can only be considered as exploratory because there was no overall Type I error rate control, and any nominal “statistical significance” claim (nominal $p \leq 0.05$) could be due to chance alone.

Additionally, the applicant conducted multiple post-hoc analyses after the data were unblinded. These post-hoc analyses could be biased as the data are unblinded and analyses can be made to produce a more favorable result. Thus, post-hoc analyses in general have a high chance of false positive findings.

In summary, FDA does not believe there is sufficient evidence to support that any of the assessed biomarkers is reasonably likely to predict clinical benefit. Considering the potential mechanism of action of MSC-NTF, which may involve multiple pathways, it is challenging to use biomarker data to support effectiveness of MSC-NTF based on exploratory analyses of multiple biomarkers. There were also large amounts of missing data. In the case of NfL, which is released into the CSF by damaged or degenerating axons, higher reduction from baseline at Week 20 of CSF NfL levels were seen in subjects with poorer efficacy outcome (measured by ALSFRS-R score changes from baseline at Week 28), the opposite of what would be expected. These findings could be due to 50% of missing NfL data at Week 20 and relatively overall small changes in NfL in MSC-NTF group. Either way in the setting of negative phase 3 study results, the findings related to NfL do not appear to provide direct evidence on treatment effect through changes in NfL.

* * *

6.2 Safety Summary

- (1) The higher incidence of deaths in the MSC-NTF group which indicates lack of survival benefit of MSC-NTF and warrants further investigation.
- (2) There appears to be a higher incidence of respiratory failure and dysphagia in the MSC-NTF group.
- (3) There appears to be a higher incidence of pain (e.g., coccydynia and back pain) in the MSC-NTF group.

(Emphasis added).

60. That same day, *Reuters* published an article titled, “US FDA panel votes against BrainStorm’s ALS therapy over effectiveness concern,” summarizing the Committee’s decision, stating the following in relevant part:

The U.S. Food and Drug Administration’s (FDA) staff reviewers said on Monday there is not enough evidence to support NurOwn’s effectiveness and that there are large amounts of missing data in the company’s application.

“Providing false hope can be ethically problematic and false hope is provided when the probability of a positive outcome is overestimated. And I think that seems to be the case here,” said Lisa Lee, one of the panelists.

61. On this news, Brainstorm’s share price fell \$0.19 per share, or 48.72%, to close at \$0.2 per share on September 28, 2023.

DAMAGES TO BRAINSTORM

62. As a result of the Individual Defendants’ wrongful conduct, Brainstorm disseminated false and misleading statements and omitted material information to make such statements not false and misleading when made. The improper statements have devastated Brainstorm’s credibility. Brainstorm has been, and will continue to be, severely damaged and injured by the Individual Defendants’ misconduct.

63. Indeed, the Individual Defendants’ false and misleading statements as alleged above, has subjected Brainstorm to the Securities Class Action.

64. As a direct and proximate result of the Individual Defendants’ actions as alleged above, Brainstorm has incurred damages from, *inter alia*: (1) costs and expenses related to the

Securities Class Action; and (2) excessive and unwarranted compensation given to the Individual Defendants based on the Company's artificial financial condition and prospects.

65. Brainstorm's market capitalization has also been substantially damaged, losing millions of dollars in value as a result of the conduct described herein.

66. Moreover, these actions have irreparably damaged Brainstorm's corporate image and goodwill. For at least the foreseeable future, Brainstorm will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Brainstorm's ability to raise equity capital or debt on favorable terms in the future is now impaired.

PLAINTIFF'S DEMAND AND DERIVATIVE ALLEGATIONS

67. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

68. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress the Individual Defendants' breaches of fiduciary duties.

69. Plaintiff is an owner of Brainstorm common stock and was an owner of Brainstorm common stock at all times relevant hereto.

70. Plaintiff will adequately and fairly represent the interests of the Company and its stockholders in enforcing and prosecuting its rights.

71. As a result of the facts set forth herein, Plaintiff has not made any demand on the Brainstorm Board to institute this action against the Individual Defendants. Such a demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

72. At the time this action was commenced, the Board consisted of seven directors: defendants Frenkel, Arbel, Almenoff, Naor, Polverino, Yablonka, and Bairu (the “Director Defendants”). The Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

Demand is Futile as to Defendants Frenkel, Arbel, Almenoff, Naor, Polverino, Yablonka, and Bairu Because They Each Face a Substantial Likelihood of Liability

73. Defendants Frenkel, Arbel, Almenoff, Naor, Polverino, Yablonka, and Bairu all face a substantial likelihood of liability for their individual misconduct. The Director Defendants were directors either throughout, or for part of, the time of the false and misleading statements, and as such had a fiduciary duty to ensure that the Company’s SEC filings, press releases, and other public statements and presentations on behalf of the Company concerning its business, operations, prospects, internal controls, and financial statements were accurate.

74. Moreover, The Director Defendants, as directors, owed a duty to, in good faith and with due diligence, exercise reasonable inquiry, oversight, and supervision to ensure that the Company’s internal controls were sufficiently robust and effective (and were being implemented effectively), and to ensure that the Board’s duties were being discharged in good faith and with the required diligence and due care. Instead, they knowingly and consciously reviewed, authorized and/or caused the publication of the materially false and misleading statements discussed above that caused the Company’s stock to trade at artificially inflated prices.

75. The Director Defendants are not disinterested because they each face a substantial likelihood of liability in light of their false and misleading statements as outlined above.

76. The Director Defendants’ conscious and knowing making or authorization of false and misleading statements, failure to timely correct such statements, failure to take necessary and appropriate steps to ensure that the Company’s internal controls were sufficiently robust and

effective (and were being implemented effectively), failure to take necessary and appropriate steps to ensure that the Board's duties were being discharged in good faith and with the required diligence constitute breaches of the fiduciary duties of loyalty and good faith, for which the Director Defendants face a substantial likelihood of liability. If the Director Defendants were to bring a suit on behalf of Brainstorm to recover damages sustained as a result of this misconduct, they would expose themselves to significant liability. This is something they will not do. For this reason, demand is futile as to defendants Frenkel, Arbel, Almenoff, Naor, Polverino, Yablonka, and Bairu.

Demand Is Excused as to Defendants Arbel, Naor, Almenoff, and Taub Because as Members of the Audit Committee They Face a Substantial Likelihood of Liability

77. Defendants Arbel, Naor, Almenoff, and Taub, as members of the Audit Committee during the Relevant Period, participated in and knowingly approved the filing of false financial statements and allowing the Individual Defendants to repeatedly make other false and misleading statements regarding the NurOwn FDA approval process to the investing public. More specifically, as members of the Audit Committee, defendants Arbel, Naor, Almenoff, and Taub were obligated to coordinate the Board's oversight of the Company's internal control over financial reporting, disclosure controls and procedures, and code of conduct. Instead, defendants Arbel, Naor, Almenoff, and Taub, as members of the Audit Committee, failed to ensure the integrity of the Company's FDA approval process, disclosures made regarding the FDA approval process, and the Company's internal controls, as required by the Audit Committee Charter. For this reason, demand is futile as to defendants Arbel, Naor, Almenoff, and Taub.

Demand is Futile as to the Director Defendants for the Following Additional Reasons

78. Under the factual circumstances described herein, the Individual Defendants are more interested in protecting themselves than they are in protecting Brainstorm by prosecuting this

action. Therefore, demand on the Board is futile and is excused. Brainstorm has been and will continue to be exposed to significant losses due to the Individual Defendants' wrongdoing. Yet, the Director Defendants have not filed any lawsuits against themselves or others who were responsible for the wrongful conduct. Thus, the Director Defendants are breaching their fiduciary duties to the Company and face a sufficiently substantial likelihood of liability for their breaches, rendering any demand upon them futile.

79. The Director Defendants have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. These conflicts of interest precluded the Director Defendants from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct.

80. In violation of the Code, the Director Defendants conducted little, if any, oversight of the Company's internal controls over public reporting and of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public, and facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of Section 14(a) of the Exchange Act. In violation of the Code, the Director Defendants failed to comply with the law. Thus, the Director Defendants face a substantial likelihood of liability and demand is futile as to them.

81. Brainstorm has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Director Defendants have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for

Brainstorm any part of the damages Brainstorm suffered and will continue to suffer thereby. Thus, any demand upon the Director Defendants would be futile.

82. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director Defendants can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

83. The acts complained of herein constitute violations of fiduciary duties owed by Brainstorm's officers and directors, and these acts are incapable of ratification.

84. The Director Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance ("D&O Insurance") if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Brainstorm. If there is a D&O Insurance policy covering the directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Director Defendants, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Director Defendants were to sue themselves or certain of the officers of Brainstorm, there would be no D&O Insurance protection. Accordingly, the Director Defendants cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an

insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and, therefore, excused.

85. If there is no D&O Insurance, then the Director Defendants will not cause Brainstorm to sue the Individual Defendants named herein, because, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

86. Thus, for all of the reasons set forth above, all of the Director Defendants, and, if not all of them, at least two of the Director Defendants cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

CAUSES OF ACTION

COUNT I

Against the Individual Defendants for Breach of Fiduciary Duty

87. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

88. The Individual Defendants owed and owe Brainstorm fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Brainstorm the highest obligation of loyalty, good faith, due care, oversight, fair dealing, and candor.

89. All of the Individual Defendants violated and breached their fiduciary duties of loyalty, good faith, due care, oversight, fair dealing, and candor.

90. Each of the Individual Defendants had actual or constructive knowledge that: (1) Brainstorm downplayed the severity of the FDA's refusal to file letter; (2) Brainstorm continued to conceal the risks associated with the submission of the BLA; and (3) as a result, the Individual Defendants' statements about Brainstorm's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times. These actions caused severe risks to the Company and are actually causing harm to the Company by subjecting

the Company to the Securities Class Action. The Individual Defendants' actions (and inactions) could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

91. The Individual Defendants caused or allowed Brainstorm to lack requisite internal controls, and, as a result, the Company regularly made false and misleading statements regarding its attempt to seek FDA approval of NurOwn, and the likelihood of NurOwn obtaining FDA approval.

92. The Individual Defendants failed to supervise, and to exert internal controls over, and consciously disregarded responsibilities involving the Company.

93. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, Brainstorm has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. The Individual Defendants breached their fiduciary duties owed to Brainstorm and its shareholders by willfully, recklessly, and/or intentionally failing to perform their fiduciary duties. They caused the Company to waste valuable assets and unnecessarily expend corporate funds. They also failed to properly oversee Brainstorm's business, rendering them personally liable to the Company.

COUNT II

Against the Individual Defendants for Unjust Enrichment

94. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

95. The Individual Defendants received performance-based compensation tied to the financial performance of Brainstorm. Because Brainstorm's financial results were inflated during the Relevant Period as a result of the wrongdoing alleged herein, the Individual Defendants received more compensation than they would have received had the truth been known that: (1)

Brainstorm downplayed the severity of the FDA's refusal to file letter; (2) Brainstorm continued to conceal the risks associated with the submission of the BLA; and (3) as a result, the Individual Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

96. The Individual Defendants knew or should have known that the Company's representations were false and misleading, all of which resulted in Brainstorm's financial results and performance being artificially inflated due to the wrongdoing identified herein.

97. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Brainstorm.

98. To remedy the Individual Defendants' unjust enrichment, the Court should order the Individual Defendants to disgorge any performance-based compensation that was received during, or as a result of, the Individual Defendants' breach of fiduciary duties and other violations of law complained of herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Declaring that Plaintiff may maintain this derivative action on behalf of Brainstorm and that Plaintiff is a proper and adequate representative of the Company;

B. Awarding the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties and violations of the federal securities laws;

C. Ordering the Individual Defendants to disgorge any performance-based compensation that was received during, or as a result of, the Individual Defendants' breaches of fiduciary duties complained of herein;

D. Granting appropriate equitable relief to remedy the Individual Defendants' breaches of fiduciary duties and other violations of law;

E. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, and costs and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: February 14, 2024

Respectfully submitted,

BRAGAR EAGEL & SQUIRE, P.C.

/s/ J. Brandon Walker

J. Brandon Walker

Lawrence P. Eagel

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Attorneys for Plaintiff

VERIFICATION

I, Mhairi Porteous, hereby verify that I have authorized the filing of the attached Verified Stockholder Derivative Complaint (“Complaint”). I have reviewed the allegations made in the Complaint, and as to those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely on my counsel and their investigation and, for that reason, believe them to be true. I further verify that I am a current holder, and have been a holder, of Brainstorm Cell Therapeutics, Inc common stock at all relevant times.

Executed this ^{1p10} day of 02, 2024.


Mhairi Porteous (Feb 10, 2024 11:17 GMT)
Mhairi Porteous